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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,787	06/18/2002	Peter Neubauer	10806-193	9630

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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,787	NEUBAUER ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Finality of Office action mailed September 9, 2005 has been removed.

This Office action is in response to the amendment filed February 14, 2006.

Claims 1-20 are presently pending and under examination.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn.

New Objection(s) and Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tornkvist et al., 1996 (Cited in the IDS filed July 2, 2002).

Tornkvist et al. teach that protein release was studied in *E. Coli* cultivations in minimal medium under different conditions and that the energy source concentration was oscillating either due to the cultivation technique or due to an applied on/off rate concept in feed batch cultivations (Abstract, page 231, column 1, lines 1-5).

Tornkvist et al. teach further that the purpose of the investigation was to study the protein release as a consequence of oscillating glucose concentration due to the cultivation technique, scale-up heterogeneity and strain dependent properties (Paragraph bridging pages 231-232).

Tornkvist et al. also teach that the medium carbon/energy source comprises glycerol and glucose (page 232, column 1, paragraph 3, lines 5-6) and that the cultivations were designed to have an oscillating feed rate. The addition of glucose per mean time unit was the same as for the constant and oscillating feed rate cultivations wherein two different time intervals were chosen, the first interval was two minutes on and two minutes off. The glucose concentration will oscillate as a consequence of the on/off rate concept, when there is no feed the glucose uptake declines and the glucose concentration reaches zero (Page 232, column 2, lines 3-10).

Tornkvist et al. teach that the fed-batch fermentations with oscillating feed rate were designed to have repeated periods with no feed and since the glucose addition per unit time was the same the glucose concentration became higher during the feed period in the oscillating feed fermentation than the constant feed fermentation (Page 235, column 1, lines 1-3 to column 2, lines 1-4 and Fig. 1 page 232).

Thus Tornkvist et al. 1996 teach all the elements of **claims 1-7 and 10-17** and these claims are anticipated under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tornkvist et al., 1996 as applied to **claims 1-7 and 10-17** above, and further in view of Neubauer et al., 1992 (Cited in the IDS filed July 2, 2002).

Tornkvist et al. teach a method of a fermentation process in *E.coli* as mentioned above.

Tornkvist et al. do not teach that IPTG or lactose is added to the culture to induce formation of a recombinant protein.

Neubauer et al. teach a method of microbial fermentation, wherein lactose is used an inducer of recombinant protein production in *E.coli* (Abstract, page 379, lines 4-8)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lactose as an inducer of the recombinant production of proteins for the advantages of reduction in the cost of production of recombinant proteins as taught by Tornkvist et al., 1996 and Neubauer et al., 1992, see Neubauer et al. at page 743, column 1, paragraph 4 lines 2-5.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tornkvist et al., 1996 as applied to **claims 1-7 and 10-17** above, and further in view of McMullen United States Patent No. 4,788,144.

Tornkvist et al. teach a method of a fermentation process as mentioned above.

Tornkvist et al. do not teach that a temperature shift occurs at the time of induction.

McMullen teaches that a temperature shift occurs at the time of induction in *E.coli* (Abstract, lines 7-12, column 2, lines 30-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to shift the temperature at the time of induction in a process of microbial fermentation involving the recombinant production of proteins for the advantages of increase in the expression of recombinant proteins caused by the inactivation of temperature sensitive repressor proteins as taught by Tornkvist et al., 1996 and McMullen see McMullen at column 2, lines 3-6 and 30-37.

Double Patenting

Examiner acknowledges applicants filing of a Terminal Disclaimer on February 14, 2006; however certain issues still remain that need to be resolved by the applicants. Namely the applicants have failed to establish showing that the inventions were owned at the time of invention, or name the prior inventor of the conflicting subject matter.

Claim 1-20 directed to an invention not patentably distinct from **claims 1-27** of commonly assigned U.S Patent No. 6,680,181. (This rejection was explained in the previous Office action.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S Patent No. 6,680,181, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JON WEBER
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